K072518

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EXHIBIT 2

510(k) Summary

CRS Medical Diagnostics, Inc.
662 Capitol Drive
Pewaukee Wisconsin 53072
Tel 262-264-0047
Fax 262-264-0051

July 10, 2007

Contact: Robert S. Brewer, Chairman of the Board

DEC 2 0 2007

1. **Identification of the Device:**
   Proprietary-Trade Name: CRS Fibrin Analysis Catheter Testing System (FACTS)
   Classification Names: Accessory to, Percutaneous, implanted, long-term intravascular catheter, product code LJS
   Common/Usual Name: Endoluminal Brush

2. **Equivalent legally marketed devices** FAS Endoluminal Brush K012641; CRS Medical Endoluminal Brush K050889

3. **Indications for Use (intended use)** The CRS Fibrin Analysis Catheter Testing System (FACTS) is intended to collect and remove obstructing material from the internal lumen surface of an indwelling central venous catheter to restore or improve catheter flow rate, and to provide a biofilm or fibrin sample which is suitable for microbiological analysis.

4. **Description of the Device:** The CRS Fibrin Analysis Catheter Testing System (FACTS) is an accessory to peripherally inserted central catheters (PICC). Each single use FACTS kit contains complete instructions for use, 2 pr nitrile powder free gloves (med), 2 each ear loop procedure face masks, 3 each alcohol swabs, 1 each BD Lure-Loc Access Device, 2 each vacutainer tube, 1 each test brush in sheath, 1 each over wrap drape, 1 each measure tape, 1 each clamp and 1 each specimen transport bag. The testing brush consists of nylon bristles wound onto a flexible stainless steel wire. The testing brush is enclosed within a polysheath that is heat sealed at the distal end and again at the brush handle and is attached by color coded rings. The different rings indicate the diameter of the testing brush bristles.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and clinical testing indicates that the new device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2007

CRS Medical Diagnostics, Incorporated
C/O Mr. Daniel Kamm
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K072518
Trade/Device Name: CRS Fibrin Analysis Catheter Testing System (FACTS)
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: August 29, 2007
Received: September 28, 2007

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

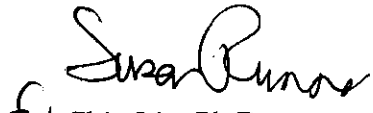
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K072518

Indications for Use

510(k) Number_____.

Device Name: CRS Fibrin Analysis Catheter Testing System (FACTS)

Indications For Use:

The CRS Fibrin Analysis Catheter Testing System (FACTS) is intended to collect and remove obstructing material from the internal lumen surface of an indwelling central venous catheter to restore or improve catheter flow rate, and to provide a biofilm or fibrin sample which is suitable for microbiological analysis.

Prescription Use X AND/OR Over-The-Counter Use ___.
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072518